**EXHIBIT E**

United States Public Health Service
Region VIII
1961 Stout Street; Room 498
Denver, Colorado 80294-3538

August 1, 2000

Dr. Linda Rosenstock, Director
National Institute for Occupational
Safety & Health
Hubert H. Humphrey Building Room 715H
200 Independence Ave., S.W.
Washington, DC 20201

Dear Dr. Rosenstock:

I would like to bring to your attention a significant occupational and public health concern regarding the widespread dissemination of amphibole (actinolite-tremolite series) asbestos in Libby, Montana, and potentially in vermiculite end-products used throughout the country. As you may be aware, NIOSH researchers evaluated vermiculite miners, that were exposed to asbestos, in Libby, Montana in the early 1980's. NIOSH investigators found significantly elevated risks of asbestos-related malignant and non-malignant respiratory disease among these workers. Concurrently, Dr. Jim Lockey at the University of Cincinnati identified elevated pulmonary disease among workers with much lower asbestos exposures at a facility processing Libby vermiculite in Ohio. These articles have been included for your information.

In November 1999, Libby became the focus of national attention when it was reported that a number of residents that did not work at the vermiculite mine or processing facilities were suffering from asbestos-related diseases. Subsequently, researchers from the Environmental Protection Agency (EPA), Public Health Service (PHS) Region 8, and Agency for Toxic Substances and Disease Registry (ATSDR) began intensive environmental and public health investigations of the site. Medical screening (e.g., chest x-rays, pulmonary function testing, questionnaires) is currently being conducted on 4200 former workers, family contacts, and others potentially at risk. NIOSH researchers (Dr. Robert Castellan, Dr. Leslie Stayner, Dr. Pat Sullivan, Dr. Vince Castranova, Mr. Ken Wallingford, and Mr. Ralph Zumwalde) have also been providing intermittent technical assistance to these efforts.

One issue that has very recently come to our attention, is that end-product vermiculite insulation, and most likely other end-products, apparently contained appreciable quantities of asbestos, but were marketed, sold, and used throughout the country without adequate labeling or warnings and were commonly considered to be non-toxic (see enclosed information and video tape). Internal company documentation and recent testing of residential insulation materials, reportedly used in over one million homes, reveals that even minimal handling by workers or residents poses a substantial health risk (airborne exposures up to 150 times the current occupational standards (0.1 f/cc)).

Recent discussions between the aforementioned federal partners working at the Libby site identified the pressing need for increased NIOSH participation and response to occupational health issues of concern.

Exemption (6)(5)

If I can be of any further assistance to you in this matter please contact me at (303) 844-7860 or Dr. Aubrey Miller at (303) 844-7857.

Sincerely,

Hugh S. Sloan

Hugh S. Sloan, D.S.W.
Assistant Surgeon General
Regional Health Administrator

Enclosures

**EXHIBIT F**

# Agency for Toxic Substances and Disease Registry

Division of Health Studies

## Preliminary Findings of Medical Testing of Individuals Potentially Exposed To Asbestoform Minerals Associated with Vermiculite in Libby, Montana: An Interim Report for Community Health Planning

February 22, 2001


DEPARTMENT OF HEALTH
& HUMAN SERVICES
Agency for Toxic Substances
and Disease Registry
Atlanta, Georgia 30333

# Preliminary Findings of Medical Testing of Individuals Potentially Exposed To Asbestoform Minerals Associated with Vermiculite in Libby, Montana: An Interim Report for Community Health Planning

February 22, 2001

Agency for Toxic Substances and Disease Registry
U.S. Department of Health and Human Services
Atlanta, Georgia 30333

Prepared by


| | |
|---|---|
| Jeffrey Lybarger, M.D. | Principal Investigator<br>Division of Health Studies, ATSDR |
| Michael Lewin, M.S. | Statistician<br>Division of Health Studies, ATSDR |
| Aubrey Miller, M.D. | Medical Officer<br>DHHS, Region VIII Office |
| Susan Kess, M.D. | Medical Officer<br>Division of Toxicology, ATSDR |

CONTENTS

# INTRODUCTION

A community-based medical testing program was developed to respond to reports of illness among persons exposed to asbestos-contaminated vermiculite in Libby, Montana. This medical testing program, a part of the Libby Community Environmental Health Project, was undertaken by the Agency for Toxic Substances and Disease Registry (ATSDR), an agency of the U.S. Department of Health and Human Services (DHHS), with the cooperation of the DHHS Region VIII Office, the U.S. Environmental Protection Agency (EPA), the Montana Department of Health and Human Services, and the Lincoln County Environmental Health Department. This medical testing program was implemented during July through November of 2000.

The principal goal of the medical testing program is to identify the asbestos-related health effects of participants exposed to asbestos from the vermiculite mine near Libby, Montana, and to refer these individuals for additional medical evaluation. Other important goals of the program are to

(a) provide EPA with information needed to identify and eliminate current exposures to asbestos in the community;

(b) identify the types of illnesses experienced by participants exposed to asbestos in order to better inform local physicians; and

(c) provide the local health care community with an estimate of the additional resources necessary to address health care needs in the Libby area during the next 10–20 years.

*This interim report has been specifically prepared for the residents, public officials, and health care practitioners of Libby, in order to assist them in preparing estimates of the community's additional health care needs and in seeking the resources required to provide the additional care.*

The data in this interim report provide a summary of the testing program's results for the first 1,078 (18%) of the total 6,144 participants. The reported prevalence of the identified medical abnormalities can be expected to change when the analyses are conducted on the complete, final data of all participants. There may be other limitations in this interim data regarding how representative these 1,078 participants are of all 6,144 participants. These limitations are important to understand in order to avoid drawing inappropriate conclusions from preliminary data

## BACKGROUND OF PROJECT

### Public Health Concerns

Commercial vermiculite from Zonolite Mountain, located approximately 6 miles from the city of Libby, Montana, was mined and milled from 1924 through 1990. This operation included strip mining for the ore, transporting it by truck to a sorting facility and to processing plants in downtown Libby, expanding the ore by heating, and shipping it by rail as a commercial product. A transfer facility was located at the base of the mountain, approximately 3 miles from Libby. Two expansion ("popping") facilities operated at different time periods in the city; these plants heated vermiculite to expand (or "pop") the crystals.

To date, the toxicity of vermiculite has not been completely studied; however, it is believed that the toxic effects associated with vermiculite exposure are related to the presence of asbestoform minerals present in vermiculite ore and released during mining and processing operations. Ore taken from the Libby mining operation has been documented to be contaminated with asbestoform minerals, including tremolite, actinolite, and others [Atkinson et al.1982 and Lockey 1984] Asbestos minerals fall into two groups or classes—serpentine and amphibole. Serpentine asbestos contains the mineral chrysotile. Minerals in the amphibole class are actinolite,

anthophyllite, amosite, crocidolite, and tremolite. For the remainder of this document (unless otherwise specified), the term "asbestos" or "asbestos-related" refers generally to asbestoform minerals associated with vermiculite mined near Libby, Montana.

Previous studies by the National Institute of Occupational Safety and Health (NIOSH) [Amandus et al. 1987a, 1987b, 1987c] and McGill University found that former workers of the mine in Libby had substantial occupational exposure to asbestos. These studies also documented significantly increased rates of pulmonary abnormalities and disease (asbestosis and lung cancer) among former workers [McDonald et al. 1986]. In addition to former workers at the mine, cases of asbestos-related pulmonary impairment have been reported among household contacts of former mine workers. Asbestos-related disease also has reportedly occurred among other residents of the community with no known direct connection with the mining operation. This is extremely unusual and suggests that asbestos exposure occurred in Libby from alternative (non-occupational) exposure pathways. Some potentially important alternative pathways for asbestos exposure that existed in the past might be related to elevated concentrations of asbestos in ambient air [EPA 1982], and recreational exposures to children playing in piles of vermiculite. Currently, some potentially important pathways of exposure may be associated with vermiculite placed in walls and attics as thermal insulation, and for use as a soil amendment or aggregate in driveways and gardens.

In the fall of 1999, the EPA Region VIII Office began an emergency response action to identify and control asbestos contamination in the Libby community. In support of this action, EPA sought assistance from the DHHS Region VIII Office, the Montana Department of Health and Human Services, and the Lincoln County Environmental Health Department to address the public health implications of past human exposure to asbestoform minerals in Libby. Concurrently, Senator Max Baucus (D-Montana) asked DHHS Secretary Shalala for the department's assistance

in addressing the need for medical testing of Libby residents for possible asbestos-related health effects This request was referred to ATSDR, the lead DHHS agency responsible for providing this type of assistance.

Asbestos-Related Diseases

Inhalation of asbestos fibers from asbestoform minerals suspended in air can result in lung diseases, such as asbestosis, mesothelioma, and lung cancer. The risk of developing any one of these diseases depends upon many factors; including the type of fiber, level of exposure, duration of exposure, and smoking history of the exposed individual.

*Pleural Changes*

Asbestos exposure is associated with several changes in the pleura (lining of the lungs and internal chest wall). These changes include plaques (circumscribed pleural thickening), diffuse pleural thickening, calcifications, and pleural effusions (accumulations of fluid in the pleural space). They indicate past exposure to asbestos, and can often be detected in chest radiographs (CXR), also known as X-rays. On the chest radiographs, these changes appear as areas of either diffuse or circumscribed thickening of the pleura.

The latency of asbestos related *pleural effusions* on chest radiograph is usually less than 20 years and is often the first indication of asbestos-related disease. Pleural effusions, depending on the severity, may be associated with shortness of breath, chest pain, and functional lung impairment. The latency time for development of asbestos-related *pleural plaques* is on average 20 years, with a range of 3 to 57 years. Clinically, circumscribed pleural plaques found on chest radiograph, in the absence of other abnormalities, are viewed as non-symptomatic "markers of exposure" and the majority of cases will not progress to significantly affect lung function. *Diffuse pleural thickening* may also be seen on chest radiograph and, depending on the severity, may be associated with

cough, shortness of breath, and functional lung impairment. The presence of any of these pleural abnormalities on chest radiograph, associated with asbestos exposure, indicates increased risk for mesothelioma and lung cancer.

*Asbestosis*

Asbestos fibers can reach the lower lung, penetrate airway walls, and pass through lung parenchyma to the pleura. They initiate fibrosis by stimulating the persistent release of various inflammatory mediators and fibroblast growth factors. The condition "asbestosis" classically refers to the occurrence of diffuse interstitial fibrosis which results from this persistent inflammatory process in response to asbestos fibers located in the interstitial or parenchyma tissues of the lung. Asbestos fibers located in or near the lung pleura appear to trigger a similar inflammatory process which frequently results in pleural thickening and the formation of calcified plaques.

The latency period (the time interval between exposure and disease) for the onset of disease typically is 10–20 years after the initial exposure, but some cases progress more rapidly. The diagnosis of asbestosis is usually based on the results of a medical and exposure history, physical examination, chest radiographs and other radiographic procedures, and pulmonary-function testing (spirometry). Clinically, asbestosis may present as a dry cough or shortness of breath with exertion. On physical examination, rales (dry crackling sounds) frequently occur with deep inspiration. The disease can vary from asymptomatic, to disabling, to potentially fatal. In advanced stages, clubbing (thickened fingertips) can result.

*Lung Cancer*

Exposure to asbestos is associated with an increased risk of developing lung cancer. The risk is related to cumulative asbestos exposure, i.e , the greater the exposure, the greater the risk of

developing lung cancer. The risk for lung cancer among smokers exposed to asbestos is much higher than it would be if the two risk factors were additive in nature.

Typically, a substantial latency period of 10–40 years occurs between initial exposure and the onset of lung cancer [ATSDR 1995]. The initial symptoms of lung cancer are variable and may include cough, chest pain, and loss of appetite. Lung cancer is often an incidental finding on a chest radiograph taken for another medical purpose.

*Mesothelioma*

Mesothelioma is a rare and generally fatal cancer of the mesothelial cells of the pleura or peritoneum. The prevalence of mesothelioma is strongly associated with asbestos exposure, but its prevalence does not correlate with the magnitude of the exposure. That is, some cases of the disease have resulted after exposure to relatively low levels of asbestos for short time periods [Becklake 1976]. Often, the latency period is 30–40 years.

Individuals with pleural mesothelioma generally present with chest pain and shortness of breath. The initial symptoms associated with peritoneal mesothelioma are weight loss, and abdominal pain and swelling. These symptoms usually do not appear until the disease is quite advanced. Currently no effective treatment exists for malignant mesothelioma.

## METHODS

### Medical Testing Program

During July through November, 2000, medical testing was provided to former workers of W.R. Grace Company, household contacts of former workers, and individuals who resided, worked, attended school, or participated in activities in the Libby area for 6 months or more before

December 31, 1990. All 1,078 of the participants included in this interim report were tested in Libby. Medical testing consisted of a verbally administered questionnaire, chest radiographs and simple spirometry testing (a measurement of lung function).

*Questionnaires*

A questionnaire was administered to obtain health-related information, including demographic characteristics, residential history, occupational history, behavior patterns that relate to asbestos exposures, and self-reports of illnesses of interest to the community or possibly related to asbestos exposure.

*Chest Radiographs*

For adults, the medical test of choice for identifying asbestos-related changes in the parenchyma and pleura of the lungs is the chest radiograph. The advantages include ready availability, low cost, and low radiation dose compared with other techniques [McLoud 1992]. Screening for asbestos-related abnormalities is usually done with a posterior-anterior (P-A) view, or with P-A *and* lateral views. However, physicians treating patients from Libby with asbestos-related pulmonary abnormalities had reported a predominance of pleural disease. Therefore, after consultation with experts in pulmonary medicine, the lateral chest view was replaced with two oblique views, to improve the test's sensitivity for detecting pleural abnormalities.

Chest radiographs for participants 18 or more years of age included posterior-anterior (P-A), right anterior-oblique, and left anterior-oblique views. For safety purposes, women of childbearing age were informed that they should postpone receiving a chest radiograph if they were pregnant. Chest radiograph was not offered to participants under 18 years of age. The equipment and procedures used to obtain the chest radiographs complied with guidelines developed by NIOSH [Sargent 1982]. The radiologist on site assessed the consistency and quality of each chest

radiograph taken and provided a routine, clinical, radiologic interpretation, which included recording asbestos-related changes on a summary report form. If findings on a chest radiograph suggested the need for immediate medical attention, the on-site radiologist completed a referral form, and the participant was counseled and directed to an appropriate source of medical care.

In addition to evaluation and interpretation by the on-site radiologist, participants' radiographs were evaluated by three physicians who are nationally recognized experts in asbestos-related conditions, as well as certified "B-readers," physicians certified by NIOSH as qualified to interpret radiographs for environmental dust-related diseases. Each B-reader independently examined the chest radiographs to classify them with respect to parenchymal and pleural abnormalities associated with exposure to mineral dusts that cause pneumoconiosis. The classification standards used are those set by the 1980 protocol of the International Labour Office of the World Health Organization (ILO) [ILO 1980]. Because some variability in interpretation of the same radiograph can occur among trained B-readers, researchers often choose to have radiographs reviewed by multiple radiologists who are certified B-readers. Two primary B-readers independently reviewed the chest radiographs taken on participants in the medical testing. The third B-reader independently read each radiograph that had different interpretations by the first two B-readers. The physicians recorded their interpretations on a standard form (developed by the ILO for recording B-readers' interpretations), which was modified to record the results of the oblique-view chest radiographs.

*Spirometry*

Spirometry testing provides a safe, well standardized, objective measurement of lung function, and it was offered to all participants, including those less than 18 years of age. The spirometric tests recorded (a) the forced expiratory volume in 1 second (FEV1 ); (b) the volume that can be expired after a maximal inhalation, typically called the forced vital capacity (FVC); and (c) their

calculated ratio (FEV1/FVC).

The two major types of abnormal ventilation identified by spirometry are called restrictive and obstructive patterns. The obstructive pattern results from decreases in expiratory flow rates. Additionally, both FEV1 and the FEV1/FVC ratio are both decreased. Examples of obstructive diseases are asthma, chronic bronchitis, and emphysema. The restrictive pattern results from decreases in pulmonary air volumes associated with parenchymal disease (as in sarcoidosis or pneumoconiosis) or extraparenchymal disease (as with neuromuscular or chest-wall disorders). In this pattern, the FVC is typically reduced, although the FEV1/FVC could remain normal. Patients with asbestos-related pulmonary impairment typically demonstrate restrictive abnormalities on spirometry testing.

Spirometry testing followed the American Thoracic Society's guidelines and was performed by a qualified technician. Established procedures were followed to ensure correct technique, calibration methods, and maintenance. Qualified medical oversight was established to monitor the test results, to ensure the quality of the results and validity of interpretations. The results were compared with normative population data on the basis of the participant's age, height, and sex.

**Procedures Used for Data Analyses**

This medical testing program was designed to identify participants with asbestos-related abnormalities and to refer them for diagnosis and follow-up treatment by private practitioners. The program was not a formal epidemiologic study with comparison groups and random samples. Nevertheless, the data collected provides important information about the prevalence and degree of asbestos-related abnormalities among Libby residents, and about the possible relationships between these abnormalities and each of the several exposure pathways evaluated.

The key outcome variable in this report is the presence of asbestos-related abnormalities on chest radiographs. The presence of abnormalities was classified in two ways (1) abnormalities identified by at least one physician and (2) abnormalities identified by at least two of three B-readers. The second classification is more stringent and also added the requirement that the abnormality was likely related to asbestos. The second classification typically is used in epidemiologic studies of asbestos-related disease. In this analyses, several case definitions were considered on the basis of whether (a) the results were to be used for epidemiologic characterization or clinical referral, (b) the abnormality was interstitial or pleural, and (c) the chest radiograph view used for classification was P-A, oblique, or a combination of these. Other adverse health effects considered were self-reported conditions, malignant outcomes associated with asbestos exposure (such as cancer abnormalities), and restrictive abnormalities (based on the pulmonary function test evaluations). Information is also included in this report that shows the number and proportion of participants with self-reported conditions associated with asbestos. The objective of the data analyses was to characterize the proportion of participants with various health outcomes within exposure. categories in the population tested. In addition, important associations between these health outcomes and the participants' exposure histories were sought.

Questionnaire and chest radiograph data were merged to create a computerized master file that contained demographic data, environmental exposure data, self-reported health data, and medical testing data. The data used for the analyses was interim data for 1,078 study participants. The key risk factors considered were the various exposure pathways (including variables related to occupational exposure), household contact with someone who had occupational exposure, activities thought to have increased the potential for exposure, and other behaviors that involved contact with vermiculite.

For this preliminary analysis, six exposure groups were defined for the 1,078 participants. Group 1 consisted of those 127 (12%) participants who worked at W.R. Grace Company either as a worker or a secondary contractor. Group 2 consisted of 116 (11%) participants who reported occupational exposure to vermiculite but did not work at W.R. Grace Company. Group 3 consisted of 177 (16%) participants who reported being in household contact with a W.R. Grace worker but were otherwise never occupationally exposed. Group 4 consisted of 558 (52%) participants who indicated that they had some form of exposure through recreational activities (e.g. played in vermiculite piles) but were never occupationally exposed to vermiculite nor had household contact with a W.R. Grace worker. Group 5 consisted of 34 (3%) participants who were excluded from Groups 1 through 4 but had lived in a residence containing vermiculite insulation. Group 6 consisted of 53 (5%) of the remaining participants who had no apparent exposure. Although the latter group is composed of participants with no apparent, specific exposure to vermiculite, this group might have had other exposures to vermiculite which were not evaluated in this analysis.

Finally, basic demographic variables and other factors were examined. These included the following: age; sex; smoking status; history of pulmonary disease, lung cancer, autoimmune disease; and various other self-reported health conditions.

## RESULTS

*For this interim report, the analyses were restricted to basic descriptive measures (means, counts, and percentages). It is important to note that the results derived from the interim data might not be representative of results that will be obtained for the complete data set.*

The interim data set was comprised of 1,078 study participants. Of these, 159 were less than 18 years of age, so no chest radiographic tests were conducted. Fourteen study participants were missing complete exposure data, therefore their data is excluded in the exposure groups in the tables that follow. Table 1 summarizes participants' exposure histories, by age group. The largest age group represented was for participants aged 45–64 years.

Table 1. Vermiculite Exposure, by Age Group

| | 0–18 years | 18–45 years | 45–65 years | 65+ years |
|---|---|---|---|---|
| All exposure groups (1,078) | 159 (15%) | 292 (27%) | 449 (42%) | 178 (17%) |
| WRG* workers & secondary contractors (127) | 0 (0%) | 21(17%) | 75 (59%) | 31 (24%) |
| No WRG occupational contact (116) | 1 (1%) | 43 (37%) | 51 (44%) | 21 (18%) |
| Household contact (177) | 10 (6%) | 61 (34%) | 76 (43%) | 30 (17%) |
| Recreational (558) | 123 (22%) | 155 (28%) | 211 (38%) | 69 (12%) |
| Residential insulation (34) | 6 (18%) | 5 (15%) | 14 (41%) | 9 (26%) |
| No apparent exposure† (53) | 16 (30%) | 5 (9%) | 18 (34%) | 14 (26%) |

Note: Percentages may not total 100 due to rounding. Participants with incomplete records may not be included in some distributions.
*WRG = W.R. Grace Company.
†No apparent exposure (non-WRG worker, no household contact, no recreational contact).

Table 2 summarizes the exposure history of participants, by sex. Of the 1,078 participants, 509 (47%) were male, and 569 (53%) were female. Males were much more likely to have potential occupational exposure to vermiculite at the W.R. Grace Company. Eighty-six percent of W.R. Grace workers and secondary contractors were male. In contrast, 76% of those reporting household contacts were female. Sixty-four percent of those reporting no apparent exposures (as defined for this analysis) from occupational, recreational, or household contact were female.

Table 2. Vermiculite Exposure Groups, by Sex

| | Male | Female |
|---|---|---|
| All exposure groups (1078) | 509 (47%) | 569 (53%) |
| WRG* workers & secondary contractors (127) | 109 (86%) | 18 (14%) |
| No WRG occupational contact with vermiculite (116) | 81 (70%) | 35 (30%) |
| Household contact (177) | 43 (24%) | 134 (76%) |
| Recreational (558) | 239 (43%) | 319 (57%) |
| Residential insulation (34) | 13 (38%) | 21 (62%) |
| No apparent exposure† (53) | 19 (36%) | 34 (64%) |

Note: Percentages may not total 100 due to rounding. Participants with incomplete records may not be included in some distributions.
*WRG = W.R. Grace Company.
†No apparent exposure (non-WRG worker, no household contact, no recreational contact).

Tables 3 and 4 summarize participants' radiographic outcomes by exposure group classification. Table 3 summarizes the number and the proportion of participants who had a lung abnormality in their chest radiographs identified by at least one of the four physicians. Although these abnormalities can not be assumed to be asbestos related, the information provides the number of participants who were referred to their private physicians for additional evaluation. (Other participants were referred for physician evaluation for non-asbestos related changes and are not described in this report.) Thirty percent of all participants were referred for a pleural abnormality and 7% for an interstitial abnormality. The proportion was highest among participants reporting to be former W.R. Grace workers and secondary contractors, with 50% having pleural abnormalities and 15% having interstitial abnormalities. In contrast, the proportion of participants in the other five groups with pleural abnormalities ranged from 21% to 33%.

Table 3. CXR* Abnormalities (Observed by at Least One Physician), by Exposure Group

| | Pleural All Views | Interstitial P-A† View |
|---|---|---|
| All exposure groups (919) | 276 (30%) | 60 (7%) |
| WRG‡ workers & secondary contractors (127) | 63 (50%) | 19 (15%) |
| No WRG occupational contact with vermiculite (115) | 38 (33%) | 11 (10%) |
| Household contacts (167) | 49 (29%) | 8 (5%) |
| Recreation (435) | 107 (25%) | 16 (4%) |
| Residential insulation (28) | 6 (21%) | 1 (4%) |
| No apparent exposure§ (37) | 10 (27%) | 3 (8%) |

Note: Percentages may not total 100 due to rounding. Participants with incomplete records may not be included in some distributions.
†P-A = Posterior-anterior.
CXR = Chest radiograph.
‡WRG = W.R. Grace Company.
§No apparent exposure (non-WRG worker, no household contact, no recreational contact).

Table 4 summarizes the number and proportion of participants having a possible asbestos-related interstitial or pleural abnormality identified on the chest radiograph by at least two of the three B-readers (the definition used by researchers for epidemiologic studies). This table presents results for three differing chest radiographic views for pleural abnormalities (i.e., "all Views", "P-A View", "Oblique View") and one chest radiographic view of interstitial abnormalities ("P-A View") for each of the exposure groups.

The abnormalities reported in Table 4 must have been observed by at least two certified B-readers. Consistency of the two reviewers was defined as both reviewers reporting the presence of pleural changes or the presence of interstitial fibrosis with a profusion level of 1/0 or greater (ILO classification). This criteria provided a greater level of significance to the findings when at least two of the certified reviewers agreed to the presence of an abnormality and agreed that the abnormality was consistent with a pneumoconiosis. This criteria is commonly used in health

surveys and epidemiologic studies. It provides an epidemiologic definition, but it is not a clinical criteria for diagnosis. Although not a clinical diagnosis, these data provide a better estimate of asbestos-related abnormalities.

Table 4. CXR*Abnormalities (Identified by at Least Two B-Readers), by Exposure Group

| | Pleural, all views | Pleural, P-A† view | Pleural, oblique view | Interstitial, P-A† view |
|---|---|---|---|---|
| All exposure groups (919) | 170 (19%) | 137 (15%) | 103 (11%) | 11 (1%) |
| WRG‡ workers & secondary contractors (127) | 47 (37%) | 37 (29%) | 26 (20%) | 6 (5%) |
| No WRG occupational contact with vermiculite (115) | 21 (18%) | 16 (14%) | 12 (10%) | 2 (2%) |
| Household contact (167) | 33 (20%) | 31 (19%) | 20 (12%) | 1 (1%) |
| Recreational (435) | 58 (13%) | 45 (10%) | 40 (9%) | 1 (0%) |
| Residential insulation (28) | 4 (14%) | 4 (14%) | 1 (4%) | 0 (0%) |
| No apparent exposure§ (37) | 5 (14%) | 3 (8%) | 2 (5%) | 0 (0%) |

Note: Percentages may not total 100 due to rounding. Participants with incomplete records may not be included in some distributions.
*CXR = chest radiograph.
†P-A = posterior-anterior view.
‡WRG = W.R. Grace Company.
§No apparent exposure (non-WRG worker, no household contact, no recreational contact).

The typical radiologic evaluation under the ILO classification uses only one chest radiograph, the back-to-front, or posterior-anterior (P-A) view. This testing program included left and right oblique views to evaluate pleural disease. Only the P-A view was used to evaluate interstitial disease as the pathology is best observed in that view. The proportion of participants with pleural abnormality is provided by the P-A view alone, the oblique views alone, and all views combined, as reported in Table 4. If these proportions are to be compared to other surveys using the ILO system, the best parameter for comparison is the proportion of pleural abnormalities in P-A views.

Nineteen percent of all participants had pleural abnormalities identified on their chest X-rays. Most of the pleural abnormalities were observed in the P-A view, but 30 participants had pleural

changes observed on the oblique views which were not observed on their P-A views. Again, former W R. Grace workers and secondary contractors had a higher prevalence of chest radiographic abnormalities for every view, when compared with other exposure groups (statistical significance not evaluated). The two groups classified as "No WRG occupational contact with vermiculite" and "Household contacts" had a similar prevalence of abnormalities which varied by chest radiograph view. Although the prevalence of abnormalities for groups classified as "Residential insulation" and "No apparent exposure" ranged up to 14%, depending on the view, one must be especially cautious about these findings given the small size of the groups. In contrast, interstitial abnormalities were observed only in 11 participants, or 1% of the total number (919) of participants who received chest radiographs.

Table 5 summarizes restrictive abnormalities identified in the pulmonary function tests, by exposure group. Moderate-to-severe changes are defined as a forced vital capacity that is less than 70% of predicted value. This does not include participants who had significant obstructive lung changes, in whom restrictive changes could not be evaluated. Participants who reported they were former workers at W.R. Grace Company, either directly or as secondary contractors, had the highest percentage of restrictive abnormalities of all exposure groups. As with the interstitial changes seen on the chest radiographs, the number of participants with moderate-to-severe restrictive function was much lower.

Table 5. Restrictive Abnormalities in Pulmonary Function, by Exposure Group

| | Moderate-to-severe restrictive abnormalities (less than 70% of predicted values) |
|---|---|
| All groups (627) | 10 (2%) |
| WRG* workers & secondary contractors (90) | 5 (6%) |
| No WRG occupational contact with vermiculite (73) | 1 (1%) |
| Household contact (114) | 1 (1%) |
| Recreational (309) | 3 (1%) |
| Residential Insulation (14) | 0 (0%) |
| No apparent exposure† (22) | 0 (0%) |

Note: Percentages may not total 100 due to rounding. Participants with incomplete records may not be included in some distributions.
*WRG = W.R. Grace Company.
† No apparent exposure (non-WRG worker, no household contact, no recreational contact).

Participants' smoking history and self-reported respiratory symptoms also were examined by exposure groups. Forty-nine percent of study participants reported having smoked cigarettes at some time during their life. Sixty-eight percent of W.R. Grace workers reported having smoked cigarettes, compared with 32% in the "No apparent exposure" group. Sixty-six percent of W.R. Grace workers and secondary contractors reported having had pulmonary disease, compared with 32% in the "No apparent exposure" group. Nine percent of all participants reported having "arthritis, lupus, or scleroderma." The proportion of W.R. Grace workers reporting this condition was 12%, and it was 11% in the "No apparent exposure" group. Additionally, 14% of participants who had been W.R. Grace workers reported having had chest surgery, whereas no more than 5% in any of the other groups reported chest surgery.

Cancer abnormalities also were examined. Thirteen participants had lesions that might be cancer. The percentage of cancer abnormalities was 2% (2 cases) among W.R. Grace workers and 3% (1 case) in the participants with no apparent, specific route of exposure.

## DISCUSSION

Because this is an interim report based upon preliminary data, interpretations of the information need to remain limited. There could be many ways in which this preliminary data might not be a truly representative sample of the entire tested population, so the final rates of abnormalities are likely to change when the final data are analyzed.

An important finding was that 19% of the participants had pleural abnormalities (which were independently observed by two of the certified B-readers). Former W.R. Grace workers had the highest rate of pleural abnormalities (37%) which is, unfortunately, consistent with previous studies and reports.

Thirty-seven (20%) of household contacts of former W.R. Grace workers had pleural abnormalities. Even though the proportion of household contacts with identified pleural abnormalities could change, this finding causes concern, as it might represent an important historic pathway of exposure to asbestos by community residents. The proportion of pleural changes observed in the other exposure groups evaluated is 13% for those who reported contact with vermiculite during recreational activities, 14% for those who only had vermiculite insulation in their residences, and 14% of those with no apparent pathways of exposure. These rates are similar, and they could indicate a background rate for participants with neither occupational nor household-contact exposure. Unfortunately, no directly comparable Montana or U.S. population studies are available to estimate the rate of pleural abnormalities among those in Libby with no work-related exposures. Studies of differing groups within the United States believed to have no substantive work-related asbestos exposures have found the prevalence of pleural abnormalities ranging from 0.02% among blue-collar workers in North Carolina [Castellan 1985], to 0.9% among loggers in Washington and Oregon [Stilbolt 1991], to 1.8% among New Jersey residents

[Anderson 1979], and 2.3% among patients at Veterans Administration hospitals in New Jersey [Miller JA 1996]. Studies of household contacts of asbestos-exposed workers have reported the prevalence of asbestos-related pleural abnormalities ranging from 3.5% for household contacts of shipyard workers [Kilburn 1985], to 19% for household contacts of workers producing amosite asbestos products [Anderson 1979].

The proportion of interstitial abnormalities and moderate-to-severe restrictive changes on participants' spirometry tests is much smaller. This finding is consistent with clinical reports by physicians in the Libby area that patients frequently present with pleural abnormalities.

Thirteen participants were identified by the chest radiograph reviewers (B-readers) with an abnormality thought to be a possible cancerous lesion. These individuals were contacted and referred to their private physician. At present, ATSDR has not conducted a retrospective survey of referred participants to determine the final diagnosis or disposition of these findings.

Several illnesses were self-reported by participants of which two were of particular interest. First, respiratory disease was reported by 66% of the participants who were former W.R. Grace workers and secondary contractors, compared to 32% of participants in the "No apparent exposure" group. This may represent a greater susceptibility of these participants because of other underlying respiratory conditions, but this group also might be slightly older than other participants, so further analyses must adjust the rates for age in order to determine the importance of this finding.

Second, members of the community also requested that ATSDR report the findings for self-reported "arthritis, lupus, or scleroderma." Eleven percent of the participants self-reported these conditions The question did not distinguish between arthritis resulting from physical degeneration

of joints (osteoarthritis), arthritis resulting from an autoimmune pathology (such as rheumatoid arthritis), or other forms of arthritis. Thus, all respondents can not be assumed to be suffering from an autoimmune pathology. In order to clarify this concern, a more specific evaluation of participants reporting these conditions would be needed. The medical literature was searched (1980 through early 2001) for published studies regarding rheumatoid arthritis, systemic lupus erythematosis (SLE), or autoimmune diseases associated with asbestosis exposure. Only a few of these studies reported any association; i.e. three cases of rheumatoid arthritis and one case of SLE were reported with pleural thickening or asbestosis. The authors did not speculate on an association. One article on SLE suggested that there might be some evidence of an epidemiologic association [Mulherin 1993]. Asbestosis has been associated with immunologic changes (hypergammaglobulinemia, anti-nuclear antibodies, and rheumatoid factor). Mulherin states "...it is interesting to speculate that asbestosis may have predisposed to the development of SLE, given the immunological derangements seen in asbestosis." Thus, at the present time, there is only limited information about the association between auto-immune diseases and asbestosis. Also, few studies have been conducted to address Mulherin's hypothesis.

## LIMITATIONS

Information obtained through systematic survey methods or medical testing programs can have many limitations. This is especially true when the information is preliminary, as in this interim evaluation. The information presented in this report represents only 1,078 (18%) participants out of 6,144 who completed the medical testing program. The proportion of participants in this interim report with observed abnormalities can not be assumed to remain the same when the testing program's total 6,144 participants is completed and the data analyzed. The medical testing program was conducted with the principal goal of providing a service-oriented screening program in the community. Therefore, methods used by epidemiologists to limit biases (sources of

influence on trends within the findings) in the cumulative information of this interim analysis were less stringent than methods used in some epidemiologic studies. No specific effort was taken to *strictly* keep all records in chronological order by testing date. Records may have changed in chronological order by handling by the hospital and local radiologist, mailing to the expert B-readers, the use of the X-rays for clinical evaluations needed before distribution to the B-readers, or by other logistical processes in the handling of records and the creation of the data file. Although participants seen earlier in the testing program are more likely to be included in the 1,078 records summarized for this interim report, they not necessarily the same ones included in this analysis. Also, because this was not an epidemiologic study, no control group was included. These limitations are important to understand in order to avoid drawing inappropriate conclusions from preliminary data.

In other testing programs, it has been observed that the identification of individuals with abnormalities is not necessarily random over time. There could be personal reasons why some individuals seek medical care earlier or why some purposely postpone testing until late in the process. Although some report that the individuals most concerned their health might seek testing earlier, this hypothesis can not be evaluated for this report.

This testing program was not an epidemiologic study. Summary information, such as that reported in this interim report, is expected to be useful for health care planning needs in the community and for understanding the scope and natural history of the illness process to provide support for local health care providers. A perspective on the magnitude of the public health problem in the Libby area can be summarized by examining the prevalence of participants with asbestos-related abnormalities, but judgements about the extent of these abnormalities above expected values are based upon few reports in the scientific literature. Because no control group was included, direct comparisons of the occurrence of abnormalities above the expected value can not be calculated

Final estimates of the proportion of participants with asbestos-related abnormalities must await the analyses of the final, complete data for all participants. The information summarized in this interim report is primarily intended to assist the community and its public officials in documenting the need for health care planning and estimating the additional health care services that will be needed in the Libby area in the future.

## CONCLUSIONS

1. These results summarize 1,078 participants, of which 47% were male and 53% female. The age distribution of participants was as follows: 15% were less than 18 years of age, 27% were aged 18–45 years, 42% were aged 46–65 years, and 17% were 65 or more years of age (the total of 101% is due to rounding).

2. The number of participants who reported exposure to vermiculite included the following: 127 were W.R. Grace workers or secondary contractors, 116 had other work related contact with vermiculite, 177 had household contacts with W.R. Grace workers, 558 reported some recreational contact with vermiculite, 34 had vermiculite insulation in their residences, 53 had none of these exposures. (Participants were included in only one group on the basis of their greatest potential for exposure.)

3. Thirty percent of participants had a pleural abnormality that was seen by at least one physician on the chest radiograph. Those individuals were informed that they should have the finding reviewed by their private physician.

4. Nineteen percent of the participants had a pleural abnormality on their chest radiographs which was reported by at least two of the certified specialists (B-readers).

5. Pleural abnormality rates varied by exposure group: 37% of W.R. Grace workers or secondary contractors, 18% of others reporting occupational exposure to vermiculite, 20% of household contacts, 14% of those who lived in the Libby area and also reported vermiculite insulation in their residences, 16% of those who reported recreational contact with vermiculite, and 14% of other participants with no apparent exposure. (These proportions used the criteria of at least two of the three B-readers.)

6. Lung scarring (interstitial changes) and moderate-to-severe limitations in pulmonary function (restrictive changes) were much less common among the participants evaluated.

7. Lung abnormalities are being observed on the chest radiographs of participants in the medical testing program. Public officials are advised to plan accordingly for the long-term evaluation of participants exposed to vermiculite and for the care of those who may develop severe illness.

8. The findings of illness in participants with large, previously recognized exposures is consistent with clinical reports by Libby area physicians. This information is too preliminary to predict the final risk estimates for participants with lower exposure potential, such as participants with vermiculite insulation in their residences, those with infrequent past contact with vermiculite, or those who resided in the community but had no apparent exposure to vermiculite.

ATSDR
AGENCY FOR TOXIC SUBSTANCES AND DISEASE REGISTRY

# Libby Medical Testing Interim Report

February, 2001

Background:

The Agency for Toxic Substances and Disease Registry (ATSDR), in cooperation with the Environmental Protection Agency, the U.S. Department of Health and Human Services, the Montana Department of Public Health and Human Services, and the Lincoln County Environmental Health Department organized a community based medical testing program. The testing program was in response to reports of illness among persons exposed to asbestos contaminated vermiculite in Libby, Montana.

This testing program was a part of the Libby Community Environmental Health Project. The medical testing was done between July and November, 2000.

Q. What did the medical testing program do?

A. The program was designed to give each participant current information about the health of the lungs. Principal goals of the program were to identify health effects likely to be asbestos related and to refer people exposed to asbestos from the Libby vermiculite mine for additional care.

Q. Why did ATSDR prepare this report?

- To keep the community informed about the ongoing progress of the program.
- To help the community, public officials, and healthcare providers plan for long-term health care by estimating the magnitude of the need for future health care services.

Q. Who was included in this report?

A. This report included only 1,078 participants, or 18% of the total number of participants in the medical testing program.

- 47% were male; 53% were female
- 15% were under 18 years of age
- 27% were aged 18-45
- 42% were aged 46-65
- 17% were over 65 years of age.

Q. What type of exposure to asbestos did the people included in this report have?

A. A breakdown of the 1,078 participants, according to their reported type of exposure to vermiculite shows:

- 127 are former W.R. Grace workers
- 116 had work-related contact with vermiculite
- 177 had household contacts with W.R. Grace workers
- 558 had recreational contact with vermiculite
- 34 had vermiculite insulation in their homes
- 53 had no known exposure to vermiculite.

(Participants above were listed in only one exposure category, based upon the greatest exposure potential.)

Q. What are the conclusions of the interim report?

Of the 1,078 participants

- 95% reported some contact with vermiculite
- 30% of adults tested had scarring of the chest wall seen by at least one physician on the chest x-ray
- 19% of adults tested had scarring seen by at least two of the certified x-ray specialists (B-readers) on the chest x-ray.

Each exposure group had different rates of scarring of the chest wall (seen by at least two B-readers). The number of people in each group who showed scarring were:

- 37% of WR Grace workers or secondary contractors
- 20% of household contacts
- 18% of those who reported occupational exposure to vermiculite
- 14% of those who have vermiculite insulation in their homes
- 14% of other participants
- 13% of those who had recreational contact with vermiculite.

Only 1 to 5% had interstitial changes, such as scarring of the lung tissue itself.

Only 1 to 6% had moderate to severe limits in pulmonary function (restrictive changes making it difficult to breathe).

Q. What does ATSDR recommend?

A. The chest x-rays of 30% of this small number of participants in the medical testing program showed lung abnormalities. Public health and other officials should plan for

- The long-term evaluation of people exposed to vermiculite, and
- The care of those who may develop severe illnesses resulting from vermiculite exposure.

Q. What are the limitations of this report?

A. The report summarizes the results of only 18% of the participants. It may not be representative of all participants. The final conclusions based on the results of all 6,144 testing participants may be very different.

## For More Information Please Contact

Dan Strausbaugh, ATSDR Montana representative at 406-293-2728 or 2729.

Dan Holcomb, ATSDR community involvement contact toll-free in Atlanta, GA at 1-888-42-ATSDR (1-888-422-8737).

Medical Testing Program at 1-800-439-8308. For those outside of the Libby area requesting information on their eligibility for asbestos testing.

EPA/TSCA Hotline Service at 202-554-1404. For information on asbestos and other toxic substances.

**ATSDR's Web Site at www.atsdr.cdc.gov**